REMARKS

Courtesies extended to Applicants' representative during the telephone interview held on February 20, 2008, are acknowledged with appreciation. While the Interview Summary generally captures the content of the telephone interview, Applicants respectfully disagree with the assertion therein that "Effing teaches monomer A that comprises the claimed hydroxyl group." See line 6 of the continuation sheet appended to the Interview Summary. Contrary to the Examiner's assertion, Effing (WO 98/53815 A1) defines A monomers as "being selected from the group consisting of alkylacrylates containing 4 to 12 carbon atoms in the alkyl group and alkylmethacrylates containing 4 to 12 carbon atoms in the alkyl group." See page 2, lines 15-17 of Effing. As the Examiner will appreciate, the requirement that monomer A in Effing be an alkylacrylate or an alkylmethacrylate does not allow for any hydroxyl moieties to be present in monomer A, as none of these monomers comprise an hydroxyl group. There is, therefore, no contemplation in Effing of any hydroxyl groups in monomer A.

In addition, with respect to monomer B, the Examiner's observation (see lines 6-7 of the continuation sheet appended to the Interview Summary) that "Effing teaches monomer B includes hydroxyethylacrylate" must be read in context. Repeatedly throughout their disclosure, Effing asserts that "preferably, the B monomer is free of nucleophilic groups." See, for example, page 3, line 24; page 3, line 30-page 4, line 2; and claim 2 (at page 14, lines 11-13).

Indeed, of the numerous examples of B monomers set forth at page 3, lines 11-23 of Effing, only one contains a free hydroxyl group (2-hydroxyethylacrylate, HEA). One can question, however, why that compound is even included in the list of suitable monomers, since the reference, when read in its entirety, makes it clear that use of such a B monomer is disfavored. See, for example, EXAMPLE 7 at page 13 of Effing, which indicates that an adhesive prepared with HEA as monomer B suffered from a decrease in drug content of more than 10% within four weeks of storage. This stands in stark contrast to the remaining examples which evaluate the stability of the active drug in the transdermal patch. See, for example,

EXAMPLE 1 and EXAMPLE 2 (both at page 11 of Effing), which indicate that full stability is retained at both 25°C and 40°C for at least four weeks. Thus, one of skill in the art would have no motivation to use a hydroxyl-containing monomer such as HEA in the preparation of an adhesive patch containing granisetron.

Moreover, it is of note that all of the experiments conducted by Effing are carried out with tropisetron. Effing then proceeds to extrapolate the results with tropisetron to granisetron, based on the assertion that these two compounds are substantially similar both structurally and functionally (see, for example, page 1, line 23-page 2, line 2 of Effing, which suggests the interchangeability of these compounds). In view of Effing's teachings, one of skill in the art would expect that observations made with respect to tropisetron would be equally applicable to granisetron. In view of the Effing teaching that 2-hydroxyethylacrylate (HEA--the only B monomer disclosed therein that contains a free hydroxyl group) is disfavored (see, for example, EXAMPLE 7 at page 13 of Effing, which indicates that an adhesive prepared with HEA as monomer B suffered from an unacceptable decrease in drug content (more than 10% decrease) within four weeks of storage), one of skill in the art would have no expectation of success using granisetron with an adhesive such as the adhesive of Effing EXAMPLE 7. Accordingly, the results reported herein are both surprising and unexpected in view of the teachings of Effing.

By the present communication, the specification has been amended to introduce the numerical values from original claim 23 into paragraph **[0039]**, thereby providing antecedent basis for the original claim. No new matter is introduced by the subject amendment as the amended specification is fully supported by the specification as filed, including the original claims.

No claim amendments are presented at this time. Accordingly, claims 1-26 and 28-33 remain pending. The present status of all claims in the application is provided in the Listing of Claims presented herein beginning on page 3 of this communication.

Rejection under 35 U.S.C. § 112, first paragraph

The rejection of claims 23-25 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement, is respectfully traversed. Specifically, Applicants respectfully disagree with the Examiner's assertion that "it appears that the present specification does not provide support for the limitation 'the adhesive is loaded with between 3 and 12% w/w granisetron' in claim 23." See page 2, lines 14-16 of the Office Action. As acknowledged by the Examiner (see page 2, line 16 of the Office Action), claims 23-25 are originally filed claims, and therefore, are part of the specification.

However, in order to reduce the issues and expedite prosecution, paragraph **[0039]** of the specification has been amended to introduce therein the numerical values from original claim 23, thereby providing antecedent basis in the specification for the original claim.

Rejection under 35 U.S.C. § 112, second paragraph

The rejection of claim 9 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite, is respectfully traversed. Applicants respectfully disagree with the Examiner's assertion that the phrase "adapted to provide a pharmacologically effective amount of granisetron after about 2 hours" is allegedly unclear (see page 3, lines 1-6 of the Office Action). Contrary to the Examiner's assertion, the language at issue is submitted to be clear. One of skill in the art would readily understand the above-quoted language to indicate that the patch can deliver amounts of the active ingredient, granisetron, capable of doing that which granisetron is known to do, e.g., prevent nausea and vomiting in a subject undergoing chemotherapy, within 2 hours of being administered to the patient; i.e., invention patches can be administered to a patient, and within 2 hours, chemotherapy can start. Consistent with this discussion, the Examiner's attention is directed to paragraph **[0035]** of Applicants' specification, which indicates that "the patches of the present invention can already begin to show efficacy by about 2 hours. . ."

Rejection under 35 U.S.C. § 102(b)

The rejection of claims 1-26, 28-31 and 33 under 35 U.S.C. § 102(b) as allegedly being anticipated by Effing (WO 98/53815 A1) is respectfully traversed. Applicants' invention, as defined, for example, by claim 1, distinguishes over Effing by requiring an adhesive patch suitable for the transdermal administration of granisetron, wherein the adhesive is an acrylic adhesive containing non-acidic hydroxyl moieties, a physiologically effective amount of granisetron being loaded in the adhesive. Therefore, invention adhesive patches are required to contain hydroxyl moieties, but not just any hydroxyl moieties—non-acidic hydroxyl moieties.

In contrast to the present claims, which are directed specifically to adhesive patches containing granisetron, Effing is directed to adhesive patches containing either tropisetron or granisetron—suggesting that these two compounds are substantially similar both structurally and functionally (see, for example, page 1, line 23-page 2, line 2 of Effing, which suggests the interchangeability of these compounds). In view of Effing's teachings, one of skill in the art would expect that observations made with respect to tropisetron (the only compound with which Effing conducted experiments) would be equally applicable to granisetron. This would clearly teach against the present invention since Effing makes it clear that the only B monomer disclosed therein that contains a free hydroxyl group (2-hydroxyethylacrylate, HEA) is disfavored. See, for example, EXAMPLE 7 at page 13 of Effing, which indicates that an adhesive prepared with HEA as monomer B suffered from an unacceptable decrease in drug content (more than 10% decrease) within four weeks of storage. This stands in stark contrast to the remaining examples which evaluate the stability of the active drug in the transdermal patch. See, for example, EXAMPLE 1 and EXAMPLE 2 (both at page 11 of Effing), which indicate that full stability is retained at both 25°C and 40°C for at least four weeks. Thus, one of skill in the art would have no motivation to use a hydroxyl-containing monomer such as HEA in the preparation of an adhesive patch containing granisetron.

Thus, when read as a whole, Effing clearly teaches away from the use of a hydroxyl-containing monomer such as HEA in the preparation of an adhesive patch containing granisetron.

Rejection under 35 U.S.C. § 103(a)

The rejection of claim 32 under 35 U.S.C. § 103(a), as allegedly being unpatentable over Effing in view of Sanger et al. (WO 94/01095 A2), is respectfully traversed. Applicants' invention, as defined by claim 32, distinguishes over the applied art by requiring a method of treatment employing the adhesive patch of claim 1.

As noted above, Effing does not disclose or suggest the patch of claim 1. Further reliance on Sanger is unable to cure the deficiencies of Effing, since Sanger adds nothing to the consideration of what a transdermal patch for the delivery of granisetron should look like.

Conclusion

In view of the above amendments and remarks, reconsideration and favorable action on all claims are respectfully requested. In the event any matters remain to be resolved in view of this communication, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

Respectfully submitted,

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